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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,889	01/21/2004	Shubh D. Sharma	70025-US04-139	4237

55506 7590 01/04/2007  
PALATIN TECHNOLOGIES, INC.  
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CRANBURY, NJ 08512

EXAMINER
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SHIBUYA, MARK LANCE

ART UNIT	PAPER NUMBER
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1639

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/04/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/761,889

Applicant(s)

SHARMA ET AL.

Examiner

Mark L. Shibuya, Ph.D.

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) 50-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-49 is/are rejected.
- 7) ☒ Claim(s) 1-19 and 49 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/12/04 &amp; 10/13/04</u> . | 6) <input type="checkbox"/> Other: _____  |

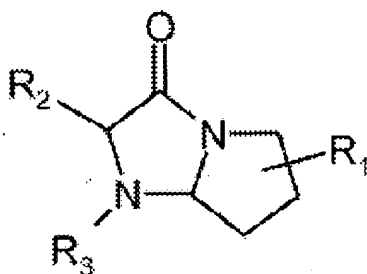
Art Unit: 1639

### DETAILED ACTION

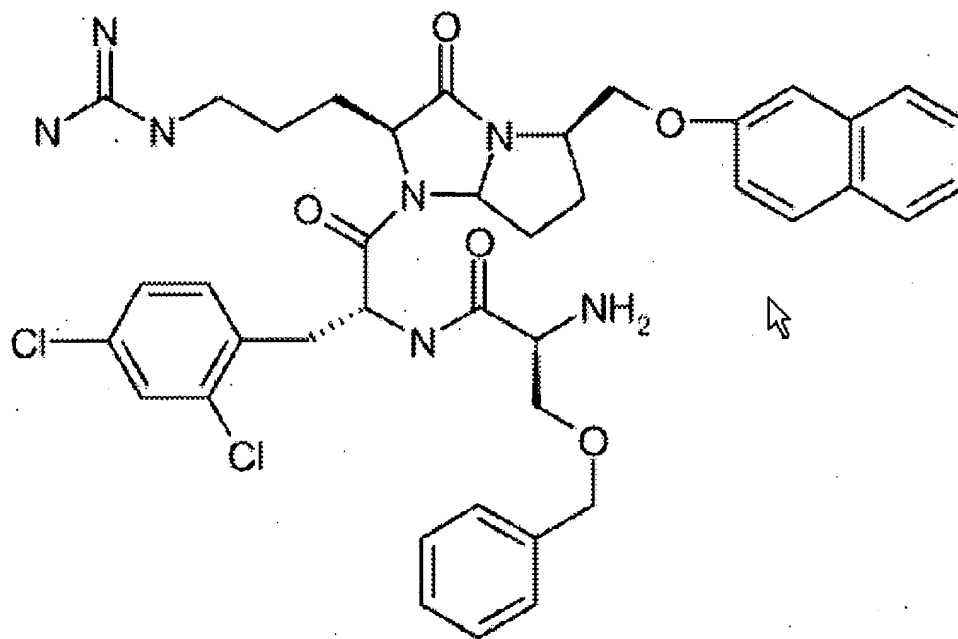
1. Claims 1-56 are pending. Claims 50-56 are withdrawn from consideration as drawn to a non-elected invention. Claims 1-19 and 49 are objected to. Claims 1-49 are examined.

### *Election/Restrictions*

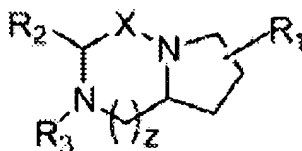
2. Applicant's election with traverse of the Invention of Group I, claims 1-49, wherein the compound is of the form:



(Election at p. 18), and an ultimate species that is:



(Election at p. 19), in the reply filed on 9/29/2006, is acknowledged. Applicant states that this election would be without traversal only if the requirement for restriction *not* depend on elected values for the variables for **J**, **W**, **Q** and **z**, on the ground that these structures do not relate to the core structure, but instead to ring structures in pendant groups. This is found persuasive as to **J**, **W**, and **Q** but it is not found persuasive as to **z**. Therefore, the requirement for restriction of invention is modified to withdraw the requirement for the variables of **J**, **W**, and **Q**. However, the requirement in regard to the variable **z** is maintained because depending on the value of **z**, (0 or 1), the core ring structure of the invention will be different, and so lack unity of invention. Generic formula I of claim 1 is reproduced below:



(Claim 1).

Furthermore, applicant argues that claims 1, 20 and 39, are linking claims that serve to link all inventions encompassed by the claims, (citing *In re Weber*, *In re Haas*; *In re Harnisch*; *Ex parte Hozumi*; and MPEP 809.03). Applicant argues that under unity of invention, as set forth in *In re Harnisch*, the claims have unity because that have a common utility (related to association with the activity melanocortin receptors) and substantially similar in core structure, because there are only two variables **z** and **X**, such that the core ring structures are narrowly and specifically drawn.

This is not found persuasive because the core ring structure of the invention will be different, depending on the values of the two variables **z** and **X**, and so lack unity of invention.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 50-56 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/29/2006.

***Priority***

4. This application, filed 1/21/2004, states that is a continuation-in-part of PCT/US02/25574, filed 8/12/2002, which claims benefit of 60/311,404, filed 8/10/2001.

***Information Disclosure Statement***

5. The information disclosure statement (IDS) filed 10/13/2004 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the citations of said IDS are duplicates of citations found in the IDS, entered 10/12/2004. It has been placed in the application file, and the information referred to therein has been considered as to the merits, but the citations on the IDS, entered 10/13/2004, have been crossed out.

***Claim Objections***

6. Claims 1-19 are objected to for being drawn, in part, to an non-elected invention.
7. Claim 49 is objected to because claim 49 states the language "of any of any of" in line 1.

***Claim Rejections - 35 USC § 112, First Paragraph***

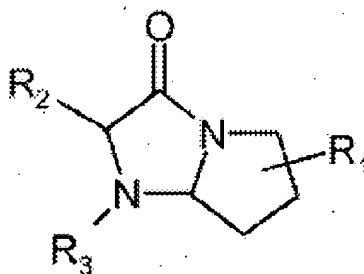
8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1639

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-49 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a compound, does not reasonably provide enablement for a pharmaceutical thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The elected invention of the claims are drawn to a molecular core ring structure that is



or a pharmaceutically acceptable salt thereof.

However, there is insufficient guidance as to how to make and use any pharmaceutical of the compound. There are many factors be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether undue experiment is necessitated. These factors can include, but are not limited to:

- (1) the breadth of the claims;
- (2) the nature of the invention;
- (3) the state of the prior art;
- (4) the relative skill of those in the art;

Art Unit: 1639

- (5) the level of predictability in the art;
- (6) the amount of direction provided by the inventor;
- (7) the existence of working examples; and
- (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

(1 and 2) The breadth of the claims and the nature of the invention: The claims recite compounds and pharmaceuticals thereof.

(3 and 5) The state of the prior art and the level of predictability in the art The publication of Hadley et al., (IDS, entered 10/12/2004), at p. 585, in contemplating the discovery and development of melanogenic drugs, state that "[t]he success of any promising new therapeutic entity depends, in large part on the development of a suitable delivery system (*i.e.*, route of administration and dosage form)."

(4) The level of one or ordinary skill: The level of skill would be high, most likely at the Ph.D. level. However, such persons of ordinary skill in this art, *given its unpredictability*, would have to engage in undue (non-routine) experimentation to carry out the invention as claimed.

(6-7) The amount of direction provided by the inventor and the existence of working examples: The specification does not provide guidance or direction for the dosage and route of administration for the treatment of any specific disease using the compounds of the claimed invention. The specification appears to provide prophetic examples of *in vivo* administration, but does not appear to provide working examples of such. The specification contemplates, as possibilities, diverse diseases that might be



Art Unit: 1639

treatable by the compounds of the claimed invention, but does not appear to provide any real guidance or direction for the treatment of disease.

(8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure: The claims contain only broad recitations to pharmaceuticals of the claimed compound. However, the instant specification does not provide to one skilled in the art a reasonable amount of guidance with respect to the direction in which the experimentation should proceed in carrying out the full scope of the claimed methods. Note that there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as broadly as it is claimed. *In re Vaeck*, 947 F.2d 488, 496 and n.23, 20 USPQ2d 1438, 1455 and n.23 (Fed. Cir. 1991). Therefore, it is deemed that further research of an unpredictable nature would be necessary to make or use the invention as claimed. Thus, due to the inadequacies of the instant disclosure, undue experimentation would be required of one of skill in the art to practice the full scope of the claimed invention.

***Claim Rejections - 35 USC § 112, Second Paragraph***

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1639

11. Claim 49 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 49 appears to be a dependent claim that does not reference a particular claim, and so is vague and indefinite. Furthermore, claim 49 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim.

### ***Conclusion***

12. Claims 1-49 are rejected. Claims 1-19 and 49 are objected to.

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

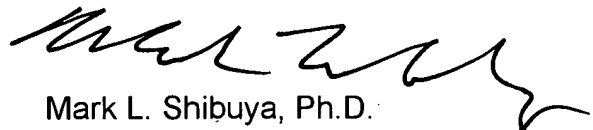
Cornille et al., Tetrahedron Letters, Vol. 35, No. 38, pp. 6989-6992, 1994.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Shibuya, Ph.D. whose telephone number is (571) 272-0806. The examiner can normally be reached on M-F, 8:30AM-5:00PM.

Art Unit: 1639

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. James Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Mark L. Shibuya, Ph.D.  
Primary Examiner  
Art Unit 1639